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Jan Grund-Pedersen

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HARNESS, DICKEY & PIERCE, P.L.C.

P.O. BOX 8910

RESTON, VA 20195

EXAMINER

GEBREMICHAEL, BRUK A

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/538,011	<b>Applicant(s)</b> GRUND-PEDERSEN ET AL.	
	<b>Examiner</b> BRUK A. GEBREMICHAEL	<b>Art Unit</b> 3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24,26,27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24,26,27 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/05/2009 has been entered.

2. Currently claims 1, 13, 20, 22, 24, 26 and 29 have been amended; claims 25, 28 and 30 have been canceled. Therefore, claims 1-24, 26-27 and 29 are pending in this application.

### ***Response to Amendments***

3. Applicant's amendment to the specification is sufficient to overcome the objection set forth in the previous office action with regard to the drawings. The Examiner accordingly withdraws the objection.

Applicant's has canceled claim 28, and amended 20. This is sufficient to overcome the claim objections set forth in the previous office action. The Examiner accordingly withdraws the objection.

Applicant's amendment to claim 22 is sufficient to overcome the 35 U.S.C 112, second paragraph rejection set forth in the previous office action with regard to claims 22 and 23. The Examiner accordingly withdraws the rejection.

### ***Claim Objections***

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4. Claim 26 is objected to because of the following informalities: the phrase "control unit **an** said interface unit" in line 3 of this claim is believed to be a typographical error for -- control unit and interface unit --. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claims 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "said instruction set" in the last line of claim 20 renders the claim indefinite since there is no limitation recited with respect to the instruction set (i.e. line 22 of claim 20 appears to be incomplete).

6. The claimed limitations "means for communication between said control unit and said interface unit" and "means for generating control signals" as recited in both claims 20 and 26; claim elements "means for simultaneously simulating handling of a number of nested instruments", "means for handling and processing said input", "means for controlling movements of a number of serially arranged and interconnected carriages", "means for simulating an effect of a first instrument inserted into a second instrument" as recited in claim 20; and the claim element "means for receiving three-dimensional information" as recited in claim 26 are means (or step) plus function limitations that invoke 35 U.S.C. 112, sixth paragraph.

Accordingly, the “means for generating signals”, “means for handling and processing said input”, appear to correspond to the computer (PC) described in the specification; the “means for simultaneously simulating handling of a number of nested instruments” appears to correspond to the interface unit described in the specification; the “means for controlling movements of a number of serially arranged and interconnected carriages” appears to correspond to the speed regulator and distance regulator described in the specification; and the “means for receiving three-dimensional information” appears to correspond to the scanning process such as MRI described in the specification.

However, with regard to the claimed limitations, “means for communication between said control unit and said interface unit” and “means for simulating an effect of a first instrument inserted into a second instrument”, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

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(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function.

For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- Claim 24 is rejected under 35 U.S.C. 102(e) as being unpatentable over Anderson 2002/0168618.

Regarding claim 24, Anderson discloses the following claimed limitations; a computer readable medium having computer readable program code embodied therein to enable an interventional procedure simulation in a system (Para.0006 and Para.0125, lines 1-7) comprising a control unit and an interface unit (FIG 4), said program comprising a communication instruction set for communication between said control unit and said interface unit (Para.0114 and FIG 3), a first instruction set for simulating handling of a number of simulated nested instruments, independently movable and rotatable, simultaneously interfaced by said interface unit (Para.0018 and Para.0035), said control unit further comprising an instruction set, comprising a second instruction set for handling and processing input from said user, a third instruction set for

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controlling said interface (Para.0125 lines 7-14), a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6, and Para.0124, lines 5-9), a fourth instruction set for generating control signals relating to an interaction between said simulated nested instruments and a surrounding geometry relating to a part of said simulated body part (Para.0033, lines 1-6 and Para.0124, lines 5-9), a fifth instruction set for calculating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each instrument having properties, being at least one of a natural shape, stiffness, length, diameter and radioopacity (Para.0071), said fifth instruction set propagated to the second instrument (FIG 5B and Para.0120), and a sixth instruction set for outputting simulation on a visualization member (Para.0097, lines 4-10).

- Claim 29 is rejected under 35 U.S.C. 102(e) as being unpatentable over Alexander 6,929,481.

Regarding claim 29, Alexander discloses the following claimed limitations; a method of an interventional procedure training (col.5, lines 54-61), using a system comprising a control unit and an interface unit (FIG 9, labels 28, 24 and 314), the method comprising using a real nested interventional procedure tool, including a first tool inserted into a second tool to be simulated in said interface device (see FIG 10, labels 302, 304 and 306), simulating an interaction between said nested first and second tools independently movable and rotatable, and a surrounding geometry relating

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to a part of said simulated body part, and using said simulation for training a user (col.16, lines 54-67).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- Claims 1-23, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson 2002/0168618 in view of Alexander 6,929,481.

Regarding claim 1, Anderson discloses the following claimed limitations, an interventional procedure simulation system, comprising a control unit and an interface unit (FIG 4), said control unit communicating with said interface unit to simulate handling of a number of real nested instruments simultaneously interfaced by said interface unit (Para.0018) and, said instruments being arranged to move and rotate independently of each other and said movements and rotations being propagated to the other instruments (Para.0018 and Para.0035), said control unit further comprising an instruction set comprising a first instruction set for handling and processing an input from a user based on said input, generating a second instruction set for controlling said interface (Para.0125, lines 7-14), a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0125, lines 17-19), a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-9), a third instruction set for generating control signals relating to an interaction



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between said simulated instruments and a surrounding geometry relating to a part of said simulated body part (Para.0125, lines 19-21).

Anderson does not explicitly disclose, a fourth instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface unit.

However, Alexander teaches, a fourth instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface unit (col.22, lines 5-18 and FIG 16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson further discloses, a fifth instruction set for calculating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each instrument having properties, being at least one of a natural shape, stiffness, length, diameter and radioopacity (Para.0071), said instruction set being configured to calculate movements of said first instrument propagated to the second instrument (FIG 5B and Para.0120).

Note that this feature is also taught by Alexander (see the *response to argument* section below for detail).

Anderson in view of Alexander teaches the claimed limitations as discussed above. Anderson further discloses,

Regarding claim 2, said interventional procedure is at least one of a diagnostic, a cardiovascular or endovascular simulation system (see Abstract lines 5-8 and Para.0012, lines 1-4),

Regarding claim 3, a user's movements of said instruments, a surrounding simulated anatomy and other present instruments, affect a shape of an instrument simulated and displayed (Para.0020 and Para.0149, lines 6-12),

Regarding claim 4, each instrument collisions with simulated surrounding calculations are executed by said control unit, which affects the shape and position of said instrument in said simulated body part (Para.0205 and Para.0206, lines 1-8),

Regarding claim 5, wherein an instrument is a distal part of a tool or an end of a tool (Para.0036, lines 1-10),

Regarding claim 6, wherein different instrument types can be used comprising at least one of balloons, stems, electrodes, wires, catheters, and distal protection(Para.0018, lines 3-8),

Regarding claim 7, wherein each instrument type has different properties associated to it and provided as an instruction set, which describes substantially all properties of said instrument (Para.0084, lines 10-16 and Para.0157, lines 1-9),

Regarding claims 8 and 9, the properties of said instruments further describe interaction with at least one of surrounding geometry, visual properties, stiffness, and

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shape; and wherein simulated properties of said instrument are altered in real-time (Para.0034, lines 3-13),

Regarding claim 10, the system comprises a model used for rendering objects depending on properties to be displayed and a collision model for computing collisions between the simulated instrument and body part (Para.0200 and Para.0205),

Regarding claim 11, a model of said body or part of said body part is a three-dimensional data obtained through a body scanning (Para.0021, lines 1-3 and Para.0128, lines 1-4),

Regarding claim 12, the instrument movements and rotations interact simulated with other instruments (Para.0035 and Para.0157, lines 9-13),

Regarding claim 13, a method for simulating an interventional procedure (Para.0032, lines 1-8), comprising the steps of providing a control unit and an interface unit (FIG 4), said control unit communicating with said interface unit to simulate handling of a number of nested real instruments simultaneously interfaced by said interface unit (Para.0018) and that each nested tool is configured to be moved and rotated independently of the other and said movements and rotations are propagated to other instruments (Para.0035), providing a first instruction set for handling and processing input from a user, generating a second instruction set based on said input, for controlling said interface (Para.0125, lines 7-14), retrieving information on said instrument comprising a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), providing a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6, and Para.0124, lines 5-9), and

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generating control signals relating to interaction between said instrument and a surrounding geometry by a third instruction set (Para.0034, lines 3-10 and Para.0125, lines 19-21).

Anderson does not explicitly disclose, controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface unit.

However, Alexander teaches, controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface unit (col.22, lines 5-18 and FIG 16).

Therefore, here also, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson further discloses, calculating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036) each instrument having properties, being at least one of a natural shape, stiffness, length, diameters and radioopacity (Para.0071) and calculating movements of said first instrument propagated to the second instrument (FIG 5B and Para.0120). Note that this feature is also taught by Alexander (see the *response to argument* section below for detail).

Anderson in view of Alexander teaches the claimed limitations as discussed above. Anderson further discloses,

Regarding claim 14, changing instrument simulated and displayed based on a user's movements of said instruments, a surrounding simulated anatomy and other present instruments, effect a shape of an instrument simulated and displayed (Para.0020, lines 7-16 and Para.0034, lines 3-13),

Regarding claim 15, wherein an instrument is a distal part of a tool or an end of a tool (Para.0036, lines 1-10),

Regarding claim 16, wherein different instrument types can be used comprising at least one of balloons, stents, electrodes, wires catheters, and distal protection (Para.0018, lines 3-8),

Regarding claim 17, wherein each instrument type has different properties associated to it and provided as an instruction set, which describes substantially all properties of said instrument (Para.0084, lines 10-16 and Para.0157, lines 1-9),

Regarding claim 18, wherein the properties of said instruments further describe interaction with at least one of surrounding geometry, visual properties, stiffness, and shape etc (Para.0035 and Para.0157, lines 9-13),

Regarding claim 19, wherein simulated properties of said instruments are altered in real-time (Para.0020, lines 7-14 and Para.0036, lines 6-16),

Regarding claim 20, a system for an interventional procedure simulation, said system comprising a control unit and an interface unit (FIG 4), the system further comprising means for communication between said control unit and said interface unit,

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means for simultaneously simulating handling of a number of nested instruments interface by said interface unit, each said instruments being, independently movable and rotatable (Para.0018; Para.0035 and Para.0157, lines 9-12), an interface member configured to receive input from a user including an instruction set, means for handling and processing said input (Para.0020, lines 7-14 and Para.0022), means for controlling said interface (Para.0022, lines 1-9), a first database configured to store characteristics for said instruments (Para.0084, lines 10-16 and also Para.0125, lines 17-19), a second database configured to store characteristics about a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-10), and means for generating control signals relating to an interaction between said simulated instruments and a surrounding geometry relating to a part of said simulated body part (Para.0034, lines 3-10 and Para.0125, lines 19-21).

Anderson does not explicitly disclose, means for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device.

However, Alexander teaches, means for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device (col.22, lines 5-18 ad FIG 16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that

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the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson further discloses, means for simulating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each instrument having properties, being at least one of a natural shape, stiffness, length, diameter, and radioopacity (Para.0071), said instruction set.

As already discussed above, this feature is also taught by Alexander (see the *response to argument* section below for detail).

Anderson in view of Alexander teaches the claimed limitations as discussed above. Anderson further discloses,

Regarding claim 21, wherein said characteristics about a body part to be simulated are obtained through a scanning process (Para.0021, lines 1-3 and Para.0128, lines 1-4),

Regarding claim 22, a computer program for interventional procedure simulation in a system comprising a control unit and an interface unit (FIG 4), said program comprising communication instruction set for communication between said control unit and said interface unit (Para.0114, lines 1-6 and FIG 3), a first instruction set for simulating handling of a number of simulated nested instruments, independently movable and rotatable, simultaneously interfaced by said interface unit (Para.0018 and Para.0035), said control unit further comprising an instruction set comprising a second instruction set for handling and processing input from a user, a third instruction set for controlling said interface (Para.0125, lines 7-14), a first data set comprising

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characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-9), a fourth instruction set for generating control signals relating to an interaction between said simulated nested instruments and a surrounding geometry relating to a part of said simulated body part (Para.0125, lines 19-21), and a seventh instruction set for outputting simulation on a visualization member (see Para.0097, lines 4-10).

Anderson does not explicitly disclose, a fifth instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device.

However, Alexander teaches, an instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device (col.22, lines 5-18 and FIG 16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson further discloses, a sixth instruction set for outputting calculating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each instrument having properties, being at least one of a



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natural shape, stiffness, length, diameter and radioopacity (Para.0071), said sixth instruction set being configured to calculate movements of said first instruction instrument propagated to the second instrument (FIG 5B and Para.0120). Note that this feature is also taught by Alexander (see the *response to argument* section below for detail).

Anderson in view of Alexander teaches the claimed limitations as discussed above. Anderson further discloses,

Regarding claim 23, a program storage device readable by a machine and encoding a program of instructions for executing the computer program for interventional procedure simulation according to claim 22 (Para.0006 and Para.0125, lines 1-7).

Regarding claim 26, a system for an interventional procedure simulation, said system comprising a control unit and an interface unit (FIG 4), the system further comprising means for communication between said control unit and said interface unit for receiving at least two nested instruments including a first instrument inserted into a second instrument, used in said interventional procedure (Para.0018 and Para.0035-Para.0036), means for receiving three-dimensional information on a body part to be simulated (Para.0021, lines 1-3 and Para.0128, lines 1-4), and means for generating control signals relating to an interaction between said first and second instruments and a surrounding geometry relating to a part of said simulated body part (FIG 5B, Para.0120 and Para.0125, lines 19-21).

Anderson does not explicitly disclose, the control signals being configured to control movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device with respect to movements of said first instrument propagated to the second instrument.

However, Alexander teaches, control signals configured to control movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device with respect to movements of said first instrument propagated to the second instrument (col.16, lines 54-67 and col.22, lines 5-18 and FIG 16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson in view of Alexander teaches the claimed limitations as discussed above. Anderson further discloses,

Regarding claim 27, wherein said three-dimensional information is obtained through a scanning process (Para.0021, lines 1-3 and Para.0128, lines 1-4).

***Response to Arguments.***

9. Applicant's arguments filled on 06/05/2009 have been fully considered. In the remarks,

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(1) Applicant argues that the cited section of Anderson is silent regarding the nesting of real instruments, as well as being silent regarding a control portion that calculates the effect of the nested instruments on one another. Rather, Anderson merely mentions that a number of tools may be interfaced but does not mention nested tools.

Moreover, Alexander fails to overcome the deficiencies of Anderson in that Alexander merely discloses an interface device and method for interfacing instruments to a medical procedure simulation system server to interface peripherals in the form of mock medical instruments to the medical procedure simulation system computer to enable simulation of medical procedures. The interface device includes a housing having a mock bodily region of interest to facilitate insertion of a mock instrument, such as an endoscope tube, into the interface device. The mock bodily region of interest may be pivotable to simulate various patient orientations. The instrument is engaged by a capture mechanism in order to measure rotational and translational motion of the instrument.

Thus, the combination of references fails to disclose or suggest calculating an effect of a first instrument inserted into a second instrument in a nested manner, each instrument having properties, being at least one of a natural shape, stiffness, length, diameter and radioopacity, said instruction set being configured to calculate movements of said first instrument propagated to the second instrument, as recited in the amended claims.

- In response to argument (1), the Examiner respectfully disagrees. The above argument appears to be based on just a particular citation of the reference. However, to

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determine whether a particular claimed feature is taught or suggested by the prior art, the entire disclosure of the applied references should be considered.

Thus, Anderson teaches or suggests the currently presented claimed feature “a fifth instruction set for calculating an effect of a first instrument inserted into a second instrument in a nested manner, each instrument having properties, being at least one of a natural shape, stiffness, length, diameter and radioopacity, said instruction set being configured to calculate movements of said first instrument propagated to the second instrument.”

For instance the line “The first user can manipulate a plurality of medical devices using the interface of the manikin. In response, **the system will simulate the movement of each of these devices** on the first user's display interface. For example, the system can simulate the can simulate **navigating a first catheter** to a target region of the body, **then a balloon catheter**, and then positioning a balloon deployment device (e.g., such as the one described above) in proximity to the balloon catheter to inflate or deflate the balloon.

In another aspect, the system also simulates **inserting a stent catheter, navigating the stent catheter to the target region, and using the balloon deployed by the balloon catheter to deploy the stent . . .**” (Para.0035 and Para.0036) describes the nesting of at least two instruments (e.g. a first catheter and a balloon catheter) working to deploy the balloon at a desired location in the body of the manikin. Note that according to Applicant's specification (e.g. see Page 5, lines 10-11), nesting implies inserting instruments into each other. The above teaching of the prior art is

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consistent with the definition implied in the specification, and therefore the Examiner concludes that Anderson teaches or suggest the above claimed feature. It is also apparent to one of ordinary skill in the art that the above instruments (e.g. stent catheter or balloon catheter or guidewire) have properties, being at least one of a natural shape, stiffness, length, diameter and radioopacity,

The prior art further teaches or suggests the limitation regarding calculating the effect of the first instrument inserted into the second instrument. For example FIG 5 of Anderson's invention teaches a tracking system for measuring the translation and rotation movement of each instrument .This tracking system is connected to a microprocessor/CPU (FIG 5B, labels microprocessor (M1) and CPU) that evaluates the movements of the devices and produce feedback. Note that the reference already discloses that the tracking system enables the intervention system to independently track the movements of two or more devices, fro example a catheter and guidewire (Para.0120). Therefore, one of ordinary skill in the art would readily recognize that Anderson's system evaluates (or calculates) the relative moment between the nested devices to produce the appropriate signal that simulates a realistic medical procedure. Of course, it is also obvious to one of ordinary skill in the art that such computation task is carried out by the microprocessor and/or CPU.

Therefore, the Examiner concludes that Applicant's currently presented claimed features have already been taught or suggested by the prior art.

Besides Anderson, Alexander also teaches or suggests the above claimed features.

For instance, FIG 10 of Alexander's invention teaches nested instruments (one instrument being inserted into another), in this case an actual or mock wire inserted into an actual or mock catheter; and the actual or mock catheter being inserted into an actual or mock sheath. In fact this type of configuration according to this reference is also referred as nesting.

For example, the line "Interface device 314 accommodates an **actual** or mock **wire 302** optionally having a handle 308, an **actual** or mock **catheter 304** optionally having a handle 310, and an **actual** or mock **sheath 306** optionally having a handle 312. **The wire, catheter and sheath are nested** and are partially disposed within the interface device. **The interface device measures manipulation** of the wire, catheter and sheath, and **provides signals** indicating the measured manipulation to **computer system 25** via communications interface 24. **Computer system 25 processes the signals** to display, via monitor 28, the internal bodily region of interest, while **adjusting the display** (e.g., vascular models) **to reflect manipulation** of the **wire, catheter and sheath.**" (col.16, lines 54-67), clearly teaches or suggests the fact that Alexander's system also implements such nested instruments (in this case wire, catheter and sheath), and the signals produced by the movement of these instruments (when performing a given medical procedure) is evaluated (calculated) by a computer to reflect the manipulation of the instruments on a display.

Therefore, the Examiner concludes that the prior art does teach or suggest Applicant's currently presented claimed features for the reasons discussed above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruk A. Gebremichael whose telephone number is (571) 270-3079. The examiner can normally be reached on Monday to Friday (7:30AM-5:00PM) ALT. Friday OFF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571) 272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Bruk A Gebremichael/  
Examiner, Art Unit 3715

/XUAN M. THAI/  
Supervisory Patent Examiner, Art Unit 3715